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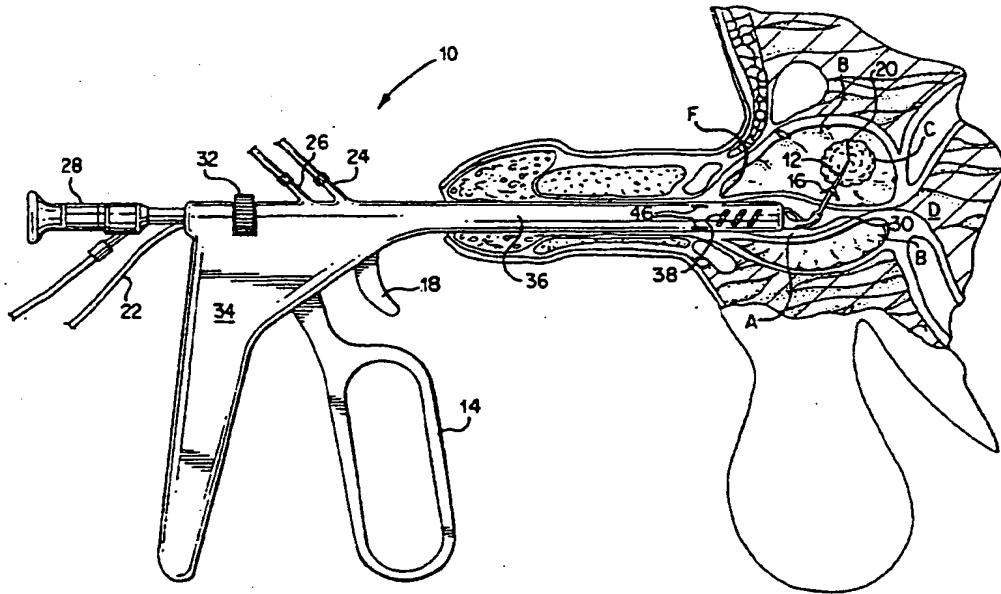
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**(54) Title:** APPARATUS AND METHOD FOR INTERSTITIAL TREATMENT



**(57) Abstract**

An apparatus and method for interstitial treatment and diagnosis in organs utilizing a flexible delivery cannula having an interstitial locking means thereon is as follows: the apparatus includes a shaft (36) for insertion into a body passage adjacent to the organ to be treated and adapted to guide cannula (12) into the organ. The shaft (36) is also adapted to receive an endoscope (28) to visualize insertion of the cannula (12). The cannula locking means (16) preferably includes an expandable locking member formed from the outer sheath of the delivery cannula at the distal end. The locking member is expanded in response to relative motion between inner and outer sheaths of the delivery cannula.

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APPARATUS AND METHOD FOR INTERSTITIAL TREATMENTRelated Application

5 The present application is a continuation-in-part of U.S. patent application No. 07/832,115, filed February 6, 1992 which is a continuation-in-part of U.S. patent application No. 07/625,332, filed December 10, 1990.

Field of the Invention

10 The present invention relates to an apparatus and method for interstitial treatment or diagnosis in organs, in particular, by insertion of an elongated shaft of the apparatus into a body passage adjacent the organ to be treated and extension of a cannula into the organ for delivery of treatment or 15 diagnosis at a selected site within the organ. More particularly, the cannula includes an interstitial locking means, preferably expandable, for reversibly locking the cannula in place after positioning and 20 during treatment.

Background of the Invention

25 Advances in medical technology have provided many new treatments and diagnostic techniques. For example, U.S. Patent No. 4,950,267 to Ishihara et al. discloses a laser beam treatment device for an endoscope. The endoscope delivers a laser probe to a position in a body, from which the laser probe is thrust into the part of the organ to be treated. 30 However, the disclosure is not too specific as how the laser probe is inserted into the organ. Also, U.S. Patent No. 5,047,026 to Rydel discloses an electrosurgical implant for cutting through tissue. The instrument includes two separate terminals at the 35 distal end that provide an arc discharge when a RF voltage is applied, thereby allowing the device to cut

tissue. No provision, however, is made for transporting the distal end to a particular treatment site with minimal damage to healthy tissue surrounding the treatment site.

5 Other treatment techniques include the implantation of radioactive seeds for radiation therapy or interstitially cell-targeted drug therapies. Also, many different types of diagnostic techniques are known, such as endoscopic or ultrasound  
10 visualization. However, suitable apparatus and methods for applying these techniques interstitially are lacking in the art

Thus, despite the numerous advances and new techniques developed for medical treatment and  
15 diagnosis, there remains in the art a need for a suitable apparatus and method to interstitially deliver such treatments to or conduct diagnosis at selected sites within an organ, without excessive and unnecessary damage to tissue surrounding the treatment  
20 site.

#### Summary of the Invention

It is therefore an object of the present invention to provide a method and apparatus for  
25 interstitially delivering various treatments or diagnoses to selected sites within an organ.

It is a further object of the invention to provide such an apparatus which can be easily and accurately manipulated by an operator to direct  
30 treatment or diagnosis to the desired interstitial location with minimal damage to surrounding tissue.

Another object of the present invention is to provide means for securing a cannula interstitially within an organ to ensure that treatment delivery or  
35 diagnosis occurs at the selected site without the

necessity of constantly monitoring the position the cannula.

These and other objects are realized according to the invention by an apparatus for

5 interstitial treatment or diagnosis in an organ which includes an elongated, and at least partially flexible delivery cannula, means for positioning the cannula in a body passage adjacent to the organ to be treated, a guide means to guide the cannula into the organ, and  
10 means for locking the cannula in place during treatment or diagnosis. Preferably, the delivery cannula is of a coaxial construction with inner and outer sheaths which are slideable with respect one another.

15 In a preferred embodiment, the inner and outer sheaths of the delivery cannula are slideable with respect to each other over substantially their entire length. However, the sheaths are secured together at the distal end. In this embodiment, the  
20 locking means comprises a portion of the outer sheath adjacent to the distal end having longitudinal slits in order to allow outward expansion of that portion in response to proximal movement of the inner sheath with respect to the outer sheath.

25 The positioning means may comprise a first rigid cannula defining an endoscope passageway and an endoscope port at the distal end and a second smaller cannula disposed within the first cannula to slideably receive the delivery cannula. The guide means  
30 preferably includes a curved distal end on at least the second smaller cannula in order to direct the delivery cannula into the tissue to be treated. According to a further embodiment, the positioning cannulae are mounted on a handle assembly which  
35 includes a gripping portion and a slider portion

extending opposite from the positioning cannulae. The coaxial delivery cannula is secured at its proximal end to the slider assembly such that distal translation of the slider assembly causes extension of

5 the delivery cannula from the distal end of the positioning means.

In a further preferred embodiment, means for affecting relative translational movement between the inner and outer sheaths of the delivery cannula in

10 order to deploy the locking means includes first, second and third members mounted on the slider assembly. The first member is secured directly to the slider assembly and defines an inner elongate space. A treatment delivery element such as a laser fiber

15 carried by the delivery cannula passes through the first member and is secured thereto. The second member is received within the elongate space of the first member and is secured to the inner sheath of delivery cannula. Preferably, the second member

20 includes two distally-extending resilient arms. The third member is received between the resilient arms of the second member and is also secured to the outer sheath. Thus, moving the second member proximally from a first position to a second position within the

25 elongate space causes translational movement of both the inner and outer sheaths over the delivery element to expose the distal end of the delivery element. Further proximal movement of the second member from the second position to a third position, while

30 preventing movement of the third member, causes relative translational movement between the inner and outer sheaths to deploy the locking member.

Brief Description of the Drawing

FIG. 1 is a view of the median sagittal section of the male pelvis illustrating the use of one embodiment of the apparatus according to the present invention for treating the prostate;

FIGS. 2-5 are a sequence of enlarged cross-sectional views of the prostate, illustrating the steps of one embodiment the method of the present invention, utilizing the apparatus shown in FIG. 1;

FIG. 6 is a schematic, partial section view of the apparatus shown in FIG. 1, illustrating a mechanism for positioning, advancing and locking the cannula according to one embodiment of the invention;

FIG. 7 is an end view of the guide wheel shown with the apparatus in FIGS. 1 and 6;

FIG. 8 is an enlarged, partial section view of the apparatus shown in FIG. 6;

FIG. 9 is an enlarged section view of the distal end of the locking cannula shown in FIG. 1, with a barb locking means according to the present invention in the retracted position;

FIG. 10 is a section view of the barb locking means shown in FIG. 9 in the extended and locked position;

FIG. 11 is a side view of the distal end of an alternative embodiment of the apparatus of the invention, similar to the apparatus shown in FIG. 1 with an extended shaft;

FIG. 12 illustrates a further alternative embodiment of the apparatus according to the invention;

FIGS. 13 and 14 illustrate an obturator and stylet, respectively, for use with the apparatus shown in FIG. 12;

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FIG. 15 is a section view of the distal end of the locking cannula of the apparatus of FIG. 12, with a barb locking in the retracted position and the stylet in place;

5 FIG. 16 is a section view of the barb  
locking means shown in FIG. 15 in the extended and  
locked position, with an energy delivery means in  
place;

FIG. 17 is a section view of the distal end  
10 of an alternative locking cannula;

FIG. 18 is a section view of the distal end of the alternative locking cannula shown in FIG. 17, with an energy delivery means in place;

15 FIG. 19 is a section view of a further alternative embodiment of the locking cannula according to the present invention;

FIG. 20 is a partially sectioned side view of a further alternative embodiment of the apparatus according to the present invention;

20 FIG. 21 is a partial plan view along line  
21-21 in FIG. 20;

FIG. 22 is a section view along line 22-22 in FIG. 20;

FIG. 24 is a right end view of the apparatus  
25 of FIG. 20;

FIG. 25 is a further side view of the apparatus of FIG. 20 showing the locking mechanism extended and viewing scope in place; and

FIGS. 26-28 are partial section views of the anchor actuating mechanism subassembly of the present invention, illustrating the sequence of positions in deploying the anchor mechanism, wherein the "A" figures represent a cross-section through a first plane and the "B" figures represent cross-section

through a second plane oriented 90° from the first plane.

Detailed Description of the Preferred Embodiments

5 In order to provide an overall understanding of the present invention, the method of the invention will be discussed with reference to laser ablation treatment of benign prostatic hypertrophy (BPH). However, it will be understood by persons of ordinary 10 skill in the art that the general method and apparatus as described herein are equally applicable treatment of any organ which is accessible through a body passage similar to the accessibility of the prostate by the urethra. For example, the prostate could be 15 approached rectally or peritoneally by laparoscopic techniques, as could other organs. Also, numerous treatments other than laser ablation are possible with the present invention.

Referring first to FIG. 1, an interstitial 20 treatment delivery apparatus 10 according to the invention is positioned in the prostatic urethra A with its distal end adjacent to the prostate B. Locking cannula 12 has been extended by squeezing hand lever 14 and the interstitial locking means 16 25 deployed by depressing trigger 18. Laser energy has been or is being delivered to treatment area C by sharpened tip 20 of laser fiber 22. An Nd:YAG or diode laser provides a suitable laser energy source. A tuneable dye laser also may be used depending on the 30 particular application. Persons of ordinary skill in the art could identify other laser sources and select suitable optical fibers for use therewith. Other components of apparatus 10 shown in FIG. 1, whose function and interrelationship will be explained in 35 detail below, are fluid ports 24 and 26, endoscope 28,

cannula guide 30, guide wheel 32, hand piece 34 and shaft 36.

After insertion of endoscope 28 into hand piece 34, shaft 36 is advanced into the prostatic urethra A while visualizing the verumontanum, as indicated by arrow 37 in FIG. 2. A dilation fluid may be introduced through one of ports 24 or 26 which communicate with distal openings 38 to facilitate introduction of the shaft. The dilation fluid can be removed through the other of ports 24 or 26, or be allowed temporarily to accumulate in the bladder D. By rotating guide wheel 32, cannula guide 30 is directed toward the wall of the urethra corresponding to the treatment zone E. Arrow 39 indicates the movement of cannula guide 30. Positioning of shaft 36 and cannula guide 30 is viewed through endoscope 28 and endoscope port 40.

Referring to FIGS. 3 and 4, as handle lever 14 is squeezed, locking cannula 12, with sharpened fiber tip 20, is exposed and directed through the urethral wall toward treatment zone E. The sharpened tip facilitates puncturing the urethral wall and pushing the cannula through the prostate. However, a sharpened laser fiber is not required. For example, as explained below, a stylet may be used for insertion of the cannula into the organ and subsequently a laser fiber (or other energy delivery means) with any desired tip may replace the stylet for treatment.

The depth of insertion into the prostate B can be determined by viewing contrasting markings 42 on the outside of cannula 12. Such contrasting markings can be on the outer surface of the cannula, for example as impregnate plastic rings, or located on an inner surface, visualizable through the cannula outer surface. Other markings are possible, the

primary requirement being the ability to be readily visualized on the cannula outer surface.

As the distal end of the locking cannula approaches the treatment zone E, ultrasound is used to 5 finely position tip 20 for treatment. The ultrasound may be applied, for example, with a transrectal ultrasound probe or by removing endoscope 28 and inserting a transurethral ultrasound probe through shaft 36. Preferably cannula 12 is provided with an 10 echogenic construction or surface treatment to improve contrast and facilitate ultrasound visualization.

Once tip 20 is in the desired position for treatment, locking means 16 are deployed as shown in FIG. 5, to positively lock the cannula in place during 15 treatment. Locking means 16 are deployed by depressing trigger 18, which causes a coaxial movement that extends barbs or other means. The various alternative configurations of locking means are described below in greater detail.

20 Referring again to FIG. 1, laser energy is shown applied through sharpened tip 20 to treat the prostate. With a sharpened tip, the area of treatment is generally spherical, with the tip located approximately at the center of the sphere.

25 During application of laser energy, it is necessary to monitor the temperature of surrounding tissue in order to prevent unwanted tissue damage. For this purpose, temperature sensing devices 46, such as thermocouples or miniaturized thermistors, are 30 placed in appropriate locations along shaft 36, and also on cannula 12 as explained below. A person of ordinary skill in the art would have sufficient knowledge to provide the necessary connections to monitoring devices and the exact locations for the 35 sensing devices.

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In high temperature energy delivery systems it is desirable to cool portions of the anatomy to prevent damage by overheating. For example, cooling fluid may be introduced through ports 24 or 26 to cool

5 shaft 36 in the region of the external sphincter F. Damage to the external sphincter could cause incontinence. It also may be desirable to extend shaft 36 distally, as shown in FIG. 11, in order to provide direct cooling to the bladder neck area G.

10 The cooling fluid may be circulated in and out of ports 24 and 26, or it may exit openings 38 and temporarily accumulate in the bladder. Accumulation in the bladder would also allow a degree of cooling of the bladder neck without a shaft extending

15 therebetween.

After treatment, the locking means is retracted and the cannula removed. Alternatively, the cannula may be repositioned and the locking means redeployed for further treatment.

20 Turning now to FIGS. 6-19, wherein like reference numerals refer to like parts, the details of the various alternative embodiments of the present invention may be described in greater detail. FIG. 6 schematically illustrates the operating mechanism of

25 apparatus 10, shown in FIG. 1. Apparatus 10 generally comprises a moveable assembly 48 and barrel 50 contained within support structure 52. Support structure 52 includes shaft portion 36 and hand piece 34. Moveable assembly 48 is mounted for both rotation

30 and axial movement, whereas barrel 50 is constrained against axial movement but does rotate with moveable assembly 48. In addition to supporting the moveable assembly and barrel, support structure 52 provides passages for flow of fluids between ports 24 and 26,

35 and openings 38. The specific arrangement of such

passages is within the skill of an ordinary skilled worker in the art and therefore they have been omitted from the drawing for reasons of clarity.

Hand piece 34 is constructed of a suitable 5 rigid material such as stainless steel or plastic in order to support moveable assembly 48 and allow for manipulation by hand.

Depending on the particular application and other factors determined by the operator, shaft 10 portion 36 can take a variety of forms. For example, it may be rigid, flexible, malleable, articulatable or expandable. Flexible embodiments may be constructed similar to known catheters. By providing controllable joints, articulatable embodiments would be well suited 15 for manipulation within the peritoneum. Expandable embodiments include longitudinal expansion by telescoping shafts and radial expansion, for example, by balloon structures on the shaft. U.S. patent application No. 07/625,332, filed December 10, 1990, 20 which is incorporated herein by reference thereto, discloses a number of shaft balloon configurations suitable for use in the shaft portion of the present invention. Balloon expandable shafts provide a locking feature in addition to the locking cannula 25 described herein and, thus, provide increased confidence in the accuracy of treatment application. Shaft balloons can also be inflated using a cooling or heat transfer medium in order to cool the body passage and surrounding tissue during energy delivery.

Moveable assembly 48 is rotated by rotating 30 guide wheel 54. This also causes barrel 50 to rotate, which positions cannula guide 30 as described above. Any suitable means for directing the cannula may serve as cannula guide 30. A preferred embodiment includes 35 a member defining a curved passage through which the

cannula slides. The moveable assembly is advanced by squeezing handle lever 14. When moved in the direction of arrow 56, the handle lever pivots at point 58 (mounted on support structure 52) and moves 5 cam member 60 forward. Cam member 60 engages lever ring 62 to cause axial movement of the moveable assembly. Lever ring 62 is fixed to moveable assembly 48. Notch 64 in cam member 60 allows lever ring 62 to rotate when the guide wheel is rotated, while at the 10 same time constantly engaging ring 62 for axial adjustment. Guide wheel 54 (FIG. 7) has an internal key 66 that cooperates with slot 68 in moveable assembly 48 to allow rotational engagement and free axial movement of the guide wheel with respect to the 15 moveable assembly.

Trigger 18 is slideably mounted on support structure 52. Trigger arm 70 includes notch 72 that cooperates with trigger ring 76 in the same manner as notch 64 and lever ring 62. However, trigger ring 76 20 is not fixed to moveable assembly 48. Trigger ring 76 moves with the moveable assembly so long as trigger 18 is not depressed. When the trigger is depressed, trigger ring 76 moves to the left as shown in FIG. 6, independent of moveable assembly 48.

25 As shown in FIG. 8, cannula 12 comprises inner sheath 80 and outer sheath 82. An energy delivery means, in this case laser fiber 22, is contained within inner sheath 80. The cannula and laser fiber are not shown in section. The cannula is 30 generally flexible to allow it to be guided by cannula guide 30 and for ease of insertion into the organ. Also, being flexible, cannula 12 is well suited for use of a steering fiber as disclosed in co-pending application No. 07/625,332 in order to provide a 35 cannula that is steerable within the organ. In

certain applications, it may be desirable to provide a rigid tip portion to facilitate insertion or increase insulative characteristics as discussed below, or to provide a rigid proximal shaft portion to enhance

5 manipulation of the cannula. As understood by a person skilled in the art, such rigid portions can be provided without compromising the general flexibility of the cannula.

Also shown in FIG. 8 is endoscope channel 81  
10 and rotary uniting rod 83. The rotary uniting rod ensures that barrel 50 rotates with moveable assembly 48, but is received in a hole to allow the moveable assembly to translate without translation of the barrel.

15 Trigger ring 76 has a forward extending, inner sheath support member 84. The support member is hollow to define a passage for the laser fiber and is secured to inner sheath 80 at joint 86. Inner sheath support member 84 is slideably received in outer  
20 sheath support member 88. The outer sheath support member extends from body 90 of the moveable assembly and is connected to outer sheath 82 at joint 92. Therefore, when lever ring 62 is advanced as explained above, outer sheath 82 moves forward and, as long as  
25 trigger 18 is not depressed, the inner sheath and laser fiber move with it to extend cannula 12 into the prostate or other organ to be treated.

Once the cannula is positioned for treatment, locking means 16 is deployed. This is  
30 accomplished by depressing trigger 18 which, through the cooperation of the elements as explained, causes inner sheath 80 to move back or proximally. Trigger ring 76 is shown in a partially depressed position in FIG. 8.

Deployment of locking means 16 according to the embodiment shown in FIG. 1 may be explained in greater detail by reference to FIGS. 9 and 10. FIG. 1 shows the use of multiple locking members, however, a 5 single locking member is shown in FIGS. 9 and 10 for clarity. FIG. 9 illustrates the distal end of the cannula as it is extended into the organ. Sharpened laser fiber tip 20 forms the piercing tip of the cannula. As discussed below, other structures such as 10 a separate stylet or hollow needle may serve this purpose. Preferably, the inner and outer sheaths are tapered at the distal end to form a profile that facilitates insertion.

Inner sheath 80 includes a shaft portion 96 15 that is constructed from helically wound wire, similar to known guide wires, in order to combine sufficient axial stiffness and pushability with bendability. At the distal end of inner sheath 80, a tip 98 is provided that carries locking barb 100 in recess 102. 20 Barb 100 can be made of any biocompatible material having sufficient strength, hardness and elasticity to be inserted and withdrawn from the surrounding tissue a number of times without failure. Such materials include stainless, carbonized or anodized steel, 25 nitinol and various hard plastics. The end of locking barb 100 is aligned with opening 104 in outer sheath 82. When inner sheath 80 is moved back as described above, locking barb 100 exits opening 104 to become implanted in the organ as shown in FIG. 10. With the 30 locking barb extended, the distal end of cannula 12 is secured adjacent to the treatment site. The operator may then release his or her grip on apparatus 10 in order to concentrate on the treatment, without the need to manually maintain the laser fiber or other 35 treatment means in place.

Locking means 16 is retracted or reversed by moving trigger ring 76 in the opposite direction from that used to deploy the locking means. This can be accomplished manually or automatically. One means

5 (not shown) for automatic retraction is to provide a spring mechanism which can be locked by the operator and, when released, biases trigger ring 76 to the retracted position.

For energy delivery treatments that involve 10 high temperature, such as laser ablation, it is preferable that tip 98 be made of a non-heat conductive material in order to prevent heat transfer to shaft portion 98. In order to monitor energy delivery and temperature, temperature sensing devices 15 46 are located along laser fiber 22 and cannula 12. In addition to thermocouples or thermistors as explained above, temperature sensing can be accomplished by fiber optic temperature sensors or infrared measuring along the cannula. Also, 20 ultrasound may be used to measure temperature remotely by tissue characterization through signal processing of the ultrasound image. The amount of tissue damage can also be determined by sensing NADPH, a compound produced by cell death.

25 Depending on the type of treatment which is to be delivered, the construction and materials for outer sheath 82 (also inner sheath 80) will vary. For high temperature energy delivery systems materials capable of withstanding the high temperatures must be 30 used. The outer sheath also must be made of an insulating or nonconductive material to prevent heat transfer down its shaft. One advantage of the present invention is that by delivering the cannula through a relatively small puncture wound, the hole heals 35 quickly and with minimal chance for infection after

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treatment. If heat transfer down the outer sheath is sufficient to cauterize the surrounding tissue, a more permanent and difficult to heal hole can be created.

Also, similar to the inner sheath, the outer sheath

- 5 must be axially stiff but bendable, although the stiffness may be provided by a guide wire-like construction of the inner sheath. As an alternative, the outer and inner sheaths can be two or more parts, with the tapered distal portion being a relatively
- 10 stiff and highly nonconductive material such as ceramic. Persons skilled in the art can identify suitable materials, such as teflon, silicon, polyurethane, polymers and copolymers, which will meet the requirements for the particular application.

- 15 To assist in ultrasound positioning, the cannula can be provided with an echogenic construction. This may result as a function of the different materials chosen for the inner and outer sheaths, or can be intentionally created, for example,
- 20 by forming the cannula with two different materials having different acoustical impedances and interfacing non-uniformly to create multiple angles of reflectance.

- 25 In certain applications it may be desirable to create a more permanent hole, for example for drainage, or to otherwise cauterize the surrounding tissue. In such instances the sheaths may be constructed of highly conductive material such that energy delivery at the tip is transferred down along
- 30 the outer sheaths. Alternatively, and in particular in non-energy delivery applications, it may be desirable to provide the cannula itself with a heat source for cauterization. For example, electric resistance heating could be used for this purpose.

Turning now to FIG. 11, there is shown an alternative embodiment of apparatus 10 having an extended shaft portion 106. An opening 108 is provided in the shaft to allow cannula guide 30 and 5 endoscope port 40 to access the urethral wall. Otherwise the construction and operation of the apparatus is substantially the same as described above. Extended shaft portion 106 is especially well suited for use of a tip balloon as disclosed in co- 10 pending U.S. application No. 07/625,332. The extended shaft can also be of sufficient length to be disposed within the bladder neck G during energy delivery in order to provide a direct cooling source thereto.

FIG. 12 illustrates a further alternative 15 embodiment of the present invention. In FIG. 12, apparatus 110 is shown substantially as it would appear in place for energy delivery treatment to an organ. An introducer assembly 112 includes shaft 114, which generally corresponds to shaft 36 in apparatus 20 10. A preferred configuration of shaft 114 is a 21-22 french stainless steel cannula, although alternatives such as those explained above in connection with apparatus 10 are also possible. Endoscope 116 is shown inserted into the introducer assembly. 25 Irrigation and light source connections 118 and 120, respectively, are also provided. The distal end of shaft 114 provides an endoscope port and forms a cannula guide 122. The direction of insertion of cannula 12 thus may be controlled by turning the 30 introducer assembly.

Locking cannula 12 enters introducer assembly 112 through port 126 and extends out of cannula guide 122. Locking actuator 130 provides coaxial movement between outer sheath 82 and inner 35 sheath 80 (shown in detail in FIGS. 15 and 16). An

energy delivery means 136 is inserted into the cannula through port 138 in locking actuator 130.

In use, the introducer assembly would first be fitted with obturator 140, shown in FIG. 13. At 5 this point neither the endoscope nor the cannula would be placed in the introducer assembly. The operator would then insert introducer assembly 112, with obturator 140, into the urethra in a similar manner to the insertion of a cystoscope. Again, as with 10 apparatus 10, the urethra and prostate are used as a reference for descriptive purposes only and not as a limitation of the invention.

After the distal end of shaft 114 is in the vicinity of the prostate or other targeted organ, 15 obturator 140 is removed and endoscope 116 is inserted with appropriate connections to the light source and irrigation. Stylet 142 is inserted into cannula 12, through port 138. Stylet 142 is shown in FIGS. 14 and 15. Cannula 12 is then inserted into the introducer 20 assembly through port 126 until it extends from cannula guide 122 and is visible through the endoscope. The introducer assembly is rotated to position the cannula in the direction of the treatment zone. Cannula 12 is then extended into the prostate 25 by gripping its proximal end and pushing or by pushing on actuator 130 to force stylet 142 into the prostate. Contrasting markings 42 on cannula 12 can be viewed through the endoscope and also with the naked eye at 30 port 126. Final positioning for treatment is again accomplished by ultrasound.

After the treatment zone is reached, inner sheath 80 is retracted using finger grips 146 and 148 of anchor actuator 130. Locking means 16 is thereby deployed as previously described. As shown in FIG. 35 16, once the distal end of cannula 12 is locked in

place, stylet 142 is removed and energy delivery means 136 is inserted to extend a predetermined distance distally out of the cannula. The amount of extension can be determined visually by markings or by a

5 mechanical stop.

FIGS. 17 and 18 illustrate another alternative embodiment of the present invention. In this embodiment, the coaxial movement of inner sheath 80 and outer sheath 82 is reversed from that shown in

10 FIGS. 15 and 16. As the treatment zone is approached, inner sheath 80 is extended forward to the final position. This action causes barb 150 to extend out of opening 152 and lock the distal end of the cannula in place. In order to assume its hook-like shape, it

15 is preferred that barb 150 be made of a material with a good elastic memory, such as nitinol. After the barb is extended, stylet 142 may be withdrawn and energy delivery means 136 inserted in its place.

Energy delivery means 136 need not be a

20 laser fiber. Other energy delivery systems which will produce the desired effect on the tissue may be used. For example, for ablation, means 136 could comprise a microwave antenna, an ultrasound probe (either a wire leading to a remote source or a piezoelectric

25 apparatus at the distal location), a radio frequency source such as a bipole located at the tip, or other thermal energy systems such as electrical resistance.

Due to the capability of removing the energy delivery means without removing the apparatus as

30 whole, the present invention is particularly well suited for multiple step therapies. For example, a photodynamic therapy may be applied using a compound which is specifically targeted to particular cells and sensitive to selected light frequencies. Such

35 targeting can be achieved by linking the compound to

monoclonal antibodies having an affinity for the target cells. The compound would be applied through cannula 12 and allowed sufficient time to reach the target cells. An optical fiber would then be inserted 5 into cannula 12 to apply laser or other appropriate light for treatment. The interstitial locking means 16 ensures that the light energy is applied at the same location as was the compound.

It is also not required that an energy 10 delivery system be used at all. After cannula 12 is locked in place by locking means 16, and stylet 142 is removed, the cannula provides an ideal conduit for other treatments such as interstitially targeted drug therapy, radiation treatment by implantation of 15 radioactive "seeds", or implantation of microwave "seeds" (essentially small metal strips) for subsequent application of microwave energy. Cannula 12 also may be used for aspiration or irrigation directly at a treatment site.

20 Additionally, cannula 12 can be used for diagnostic purposes as well as therapeutic. For example, the probe of an endoscope or ultrasound imager may be directed to a specific location in an organ. Contrast agents could be delivered to improve 25 external radiographic, magnetic resonance or ultrasound imaging.

It is not required that cannula 12 have 30 coaxial sheaths. FIG. 19 shows a further embodiment of the invention utilizing flexible needle 154 as an outer member and energy delivery means 136 to deploy locking barb 156. Locking barb 156 is secured to delivery means 136 by collar 158 and received in recess 160 in needle 154 when retracted. In use, needle 154 is inserted into the organ, to the 35 treatment location, by suitable means as described

herein. The needle is then slightly backed off and means 136 separately advanced into the treatment position, simultaneously deploying barb 156 through curved guide hole 162. Means 136 may have a tapered 5 or sharpened end to facilitate its advancement into the passage created by the needle. This embodiment is particularly well suited for application with the flexible and steerable needles and apparatus disclosed in U.S. application No. 07/625,332, which has been 10 incorporated by reference.

A further preferred alternative embodiment of the present invention is illustrated in FIGS. 20-28. As shown in FIG. 20, Apparatus 200 includes introducer or positioning cannula assembly 202, handle 15 assembly 204, and slide assembly 206. A further component, locking cannula assembly 208 for treatment delivery, is illustrated in detail in FIGS. 26-28. As best seen in FIGS. 21 and 22, introducer cannula assembly 202 comprises inner guide cannula 210 for 20 slideably receiving and guiding locking cannula assembly 208 and outer guide cannula 212 for slideably receiving a viewing scope. Outer cannula 212 defines scope viewing port 213 at the distal end. A sleeve 214 is bonded around the proximal end of outer guide 25 cannula 212. Sleeve 214 is in turn bonded into a complimentary shaped aperture in grip portion 216 of handle assembly 204. Inner guide cannula 210 extends preferably a short distance beyond the outer guide cannula to communicate with slide portion 218 of the 30 handle assembly. Seal 220 is provided around the proximal end of outer guide cannula 212 and sleeve 214 in order to provide a fluid tight aspiration/irrigation port 222 (See FIGS. 24 and 25).

Slide assembly 206 slides freely on slide 35 portion 218 of handle assembly 204. The distal motion

of slide assembly 206 is stopped by slide stop 224. Slide assembly 206 carries locking cannula assembly 208 as explained in detail below. Locking cannula assembly 208 passes through and an elongated slot (not shown) in the top of slide portion 218 in order to be received in inner guide cannula 210. The handle portion and slide assembly cooperate such that the user may comfortably grip the handle portion and push the slide assembly forward by applying pressure with 5 the thumb to control member 226 to cause the distal end of locking cannula assembly 208 to extend from the distal end of introducer assembly 202 and into the area to be treated, similar to the positions shown in FIGS. 3 and 4. Slide lock 211 prevents movement of 10 the slide assembly 206 after the locking member is deployed. 15

Once the slide assembly has been pushed forward and the locking cannula assembly inserted into the area of tissue to be treated, locking member 260 20 may be deployed. To deploy the locking member, control lever 228 is pushed upward from the position shown in FIG. 20 to approximately the position shown in FIG. 25. Control lever 228 acts on actuating lever 230 (preferably it is formed integrally therewith) to 25 cause the actuating lever to move backward in the direction indicated by arrow 232. Actuating lever 230 pivots around pin 234 mounted on the slide assembly. Slots 236 (FIG. 25) in actuating lever 230 engage the anchor actuator mechanism 238 of locking cannula assembly 208 as discussed below. Actuator mechanism 238 is slideably carried in laser port member 240. Laser fiber 242, preferably a 400 micron fiber, passes 30 through laser port 240 and into locking cannula assembly 208. The laser fiber may be secured to the 35 laser port by heat shrink tubes 244 and 246.

Referring now to FIGS. 26 through 28, the construction and deployment of the locking cannula assembly is explained. As shown in FIG. 26A, laser fiber 242 passes through laser port 240 and into locking cannula assembly 208. Locking cannula assembly 208 comprises outer sheath 248 which is bonded at its proximal end to outer sheath block 250. Preferably the outer sheath is provided an echogenic enhancing feature as previously described to facilitate positioning. Inner sheath 252 is bonded at its proximal end to inner sheath block 254. Inner sheath 252 is slideably received within outer sheath 248 over substantially all its length, except at distal end 256 where the sheaths are bonded together over a short distance.

The inner and outer sheaths are preferably made of medical grade plastic material which provides suitable stiffness while allowing sufficient flexibility to traverse around the curved distal end of inner guide cannula 210. A piercing point 258, for facilitating entry into the tissue to be treated, is provided simply by cutting the sheaths at an angle. Preferred material for the inner and outer sheaths is PET.

FIGS. 26A and B illustrate locking cannula assembly 208 both before and after slide assembly 206 is pushed forward against stop 224. As the slide assembly is pushed forward, distal end 256 emerges from inner guide cannula 210 and travels into the tissue, facilitated by piercing point 258. Preferably the forward travel of assembly 206 is about 1.65 inches.

Once the slide stop has been reached, locking member 260 may be deployed as sequentially shown in FIGS. 27 and 28. FIGS. 27A and 27B represent

an intermediate position wherein control lever 228 has been pushed approximately half way up, between the positions shown in FIGS. 20 and 25. As actuating lever 230 is moved in the direction of arrow 232 by 5 control lever 228, slots 236 cooperate with studs 262 on inner sheath block 254. Inner sheath block 252 also includes resilient arms 264 which retain outer sheath block 250 therebetween, as shown FIGS. 26B and 27B. Thus, as control lever 228 initially moves 10 backward, it moves with it both inner sheath block 254 and outer sheath block 250, sliding within the elongated space defined by laser port 240. The two blocks in turn draw back the inner and outer sheaths to expose the tip of laser fiber 242 as shown in FIG. 15 27A.

In the intermediate position thus described, the inner and outer sheath blocks have moved from position X to position Y as indicated in FIGS. 27A and B. In the Y position, resilient arm 266 on outer 20 sheath block 250 engages behind locking projection 268 on laser port member 240. Also, on the side opposite resilient arm 266, outer sheath 248 abuts against edge 270 of laser port number 240. The contact at edge 270 presents further backward movement of outer sheath 25 block 250, also preventing further backward movement 25 of the outer sheath.

In order to fully deploy locking member 260 as shown in FIG. 28A, control lever 228 is pushed fully to the position shown in FIG. 25. This causes 30 further backward movement of actuating lever 230, which, in turn, draws back inner sheath block 254 by acting on studs 262. However, because outer sheath block 250 is retained at position Y by edge 270, the backward force supplied through control lever 228 35 causes resilient arms 264 to disengage from outer

- 25 -

sheath block 250 as shown in FIG. 28B. Inner sheath block 254 thus moves back to position Z, drawing back inner sheath 252 with it.

Because the sheaths are secured together at 5 distal end 256, slots cut in outer sheath 248 allow expansion of locking member 260, to accommodate for relative movement between the sheaths. The final backward movement of control lever 228 also causes engagement of slide lock 211 to prevent movement of 10 slide assembly 206 during treatment. Referring to FIG. 20, the backward movement of lever 228 causes the forward movement of tab 280. Tab 280 acts on the upper arm of lock 211 to bias the lower arm against slide portion 218. Preferably, the lower arm is 15 provided with a knurled or serrated gripping surface 282. U-shaped lock 211 is secured in place by pin 284.

Once locking member 260 is deployed, laser energy may be safely applied through fiber 242 with 20 the operator being assured of secure placement of the fiber. When treatment is complete, the movement of control lever 228 and slide assembly 226 is reversed from that described above to undeploy member 260 and withdraw the locking cannula assembly from the tissue.

25 Provision for endoscope viewing of the positioning of the apparatus in the bodypassage and extension of locking cannula assembly 206, as previously described in other embodiments, is also made possible with the present embodiment. As best 30 shown in FIG. 24, a suitable fixture 272 is provided for receiving endoscope 274. Locking means such as lever 276 may be provided to secure the endoscope in place. Lever 276 includes a shaft (not shown) with a notch or other similar means for cooperating with a

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complimentary locking part on endoscope 274 after it is inserted into outer cannula 212.

Persons of ordinary skill in the art may select appropriate materials for construction of 5 apparatus 200. Preferably introducer assembly 202 is made of stainless steel. Unless otherwise indicated, the other components may be made of suitable medical grade plastics.

It will be appreciated by persons of 10 ordinary skill in the art that the various surface treatments described above for improving echogenicity, different treatment techniques and applications, and various positioning methods, etc., are equally applicable to apparatus 200, shown in FIGS. 20-28.

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Claims

1. An apparatus for interstitial treatment or diagnosis in an organ, comprising:

5 an elongated and at least partially flexible delivery cannula having a distal end for insertion into the organ and a proximal end, said cannula comprising an outer sheath and an inner sheath received within the outer sheath for axial movement  
10 therebetween;

means for positioning the delivery cannula in a body passage adjacent the organ, said positioning means having proximal and distal ends;

15 means for guiding the delivery cannula into the organ; and

locking means disposed on the delivery cannula adjacent to the distal end for locking said cannula in place during treatment or diagnosis.

20 2. The apparatus according to claim 1, wherein:

said sheaths are slideable relative to each other over substantially their entire lengths, with said sheaths being secured together at the distal  
25 end; and

said locking means comprises a portion of the outer sheath adjacent the distal end having longitudinal slits therein to allow outward expansion of said portion in response to proximal movement of  
30 the inner sheath with respect to the outer sheath.

3. The apparatus according to claim 1, wherein said positioning means defines a passageway for receiving an endoscope and an endoscope port

disposed to allow viewing of insertion of the cannula into the organ.

4. The apparatus according to claim 3,  
5 further comprising contrasting markings visualizable on the delivery cannula outer surface, whereby the distance of insertion of the cannula into the organ may be viewed through the endoscope.

10 5. The apparatus according to claim 3, wherein said positioning means includes a first rigid cannula defining said endoscope passageway and port and a second, smaller cannula disposed within said first cannula for slideably receiving said delivery  
15 cannula.

6. The apparatus according to claim 5, wherein said guiding means comprises a curved distal end on said first and second positioning means  
20 cannulae.

7. The apparatus according to claim 5, further comprising:

25 elongate, flexible treatment delivery element extending through said delivery cannula; body means including a gripping portion with said first and second positioning cannulae secured thereto and a slider portion extending from the gripping portion opposite said cannulae;

30 sliding assembly mounted on said slider portion for axial translation with respect thereto, said delivery cannula and delivery element being secured to said assembly such that axial translation of said assembly toward the gripping portion causes

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extension of the delivery cannula and element from the distal end of the second cannula; and  
means for effecting relative  
translational movement between the inner and outer  
5 sheaths.

8. The apparatus according to claim 7,  
further comprising at least one fluid port mounted on  
the gripping portion and communicating with the first  
10 positioning cannula for irrigation and aspiration.

9. The apparatus according to claim 7,  
wherein said means for effecting relative  
translational movement between the inner and outer  
15 sheaths comprises:

a first outer member mounted on said  
slider assembly and defining an elongated space, said  
delivery element passing therethrough and being  
secured to said first member;

20 a second, intermediate member slideably  
received within said elongate space, said second  
member being secured to the inner sheath and defining  
a space between two resilient arms; and

25 a third, inner member received in said  
space between said resilient arms, said third member  
being secured to the outer sheath;

wherein movement of the second member  
from a first position to a second position causes  
translational movement of the inner and outer sheaths  
30 over the delivery element and further movement of the  
second member from the second position to a third  
position causes relative translational movement  
between the inner and outer sheaths.

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10. The apparatus according to claim 9,  
wherein the delivery element is a laser fiber.

11. The apparatus according to claim 11,  
5 wherein the laser fiber is secured to the first, outer  
member by heat shrink tubing.

12. The apparatus according to claim 9,  
wherein:

10 the resilient arms engage the third  
inner member for movement from the first position to  
the second position with the second intermediate  
member;

15 the first member includes an abutment  
surface for contacting the third member in the second  
position and preventing movement of the third member  
to the third position thereby disengaging said  
resilient arms from the third member.

20 13. The apparatus according to claim 12,  
wherein said slider assembly includes finger actuated  
lever means cooperating with said second intermediate  
member for moving said member.

25 14. The apparatus according to claim 12,  
wherein:

said sheaths are slideable relative to  
each other over substantially their entire lengths,  
but secured together at their distal ends;

30 said locking means comprises a portion  
of said outer sheath adjacent the distal end having  
longitudinal slits therein to allow outward expansion  
of said portion of the outer sheath in response to  
proximal movement of the inner sheath with respect to  
35 the outer sheath.

15. An apparatus for interstitial treatment or diagnosis in an organ, comprising:

an elongated and at least partially flexible  
5 delivery cannula having a distal end for insertion into the organ and a proximal end, said cannula comprising an outer sheath and an inner sheath received within the outer sheath for axial movement therebetween, said sheaths being slideable relative to  
10 each other over substantially their entire lengths and secured together at the distal end;

means for positioning the delivery cannula in a body passage adjacent the organ, said positioning means having proximal and distal ends;

15 means for guiding the cannula into the organ; and

a locking portion of said outer sheath adjacent the distal end having longitudinal slits therein to allow outward expansion of said portion in  
20 response to proximal movement of the inner sheath with respect to the outer sheath, for locking the cannula in place during treatment or diagnosis.

16. The apparatus according to claim 15,

25 wherein said positioning means includes a first rigid cannula defining an endoscope passage way and a second, smaller cannula disposed within said first cannula for slideably receiving said delivery cannula.

30 17. The apparatus according to claim 16 wherein said guiding means comprises a curved distal end on said first and second positioning means cannulae.

18. The apparatus according to claim 15,  
further comprising:

elongate, flexible treatment delivery  
element extending through said delivery cannula;

5 body means including a gripping portion  
with said positioning means mounted thereon and a  
slider portion extending from the gripping portion  
opposite said position means; and

10 sliding assembly mounted on said slider  
portion for axial translation with respect thereto,  
said delivery cannula and delivery element being  
secured to said assembly such that axial translation  
of said assembly toward the gripping portion causes  
extension of the delivery cannula and element from the  
15 distal and end of said positioning means.

19. The apparatus according to claim 15,  
further comprising:

20 an elongate flexible treatment delivery  
element extending through said delivery cannula;  
means for expanding said locking  
portion, said means comprising:

25 a first outer member mounted  
with said positioning means and  
defining an elongate space, said  
delivery element passing therethrough  
and being secured to said first member,  
a second, intermediate member  
slideably received within said elongate  
space, said second member being secured  
30 to the inner sheath and defining a  
space between two distally extending  
arms, and

35 a third, inner member received in  
said space between said extending arms,

said third member being secured to the outer sheath;  
wherein movement of the second member proximally from a first position to a second position 5 causes translational movement of the inner and outer sheaths over the delivery element and further proximal movement of the second member from the second position to a third position causes relative translational movement between the inner and outer sheaths thereby 10 expanding said locking portion.

20. An apparatus for interstitial treatment or diagnosis in an organ, comprising:

an elongated and at least partially flexible 15 delivery cannula having a distal end for insertion into the organ and a proximal end, said cannula comprising an outer sheath and an inner sheath received within the outer sheath for axial movement therebetween, said sheaths being slideable relative to 20 each other over substantially their entire lengths and secured together at the distal end;

a first rigid positioning cannula adapted for insertion into a body passage, said cannula having distal and proximal ends and defining an endoscope 25 receiving passageway and an endoscope port at the distal end;

a second, smaller positioning cannula disposed within said first cannula for slideably receiving said delivery cannula, said second 30 positioning cannula having a curved distal end for guiding the delivery cannula into the organ adjacent the body passage; and

a locking portion of said outer sheath adjacent the distal end having longitudinal slits 35 therein to allow outward expansion of said portion in

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response to proximal movement of the inner sheath with respect to the outer sheath, for locking the cannula in place during treatment or diagnosis.

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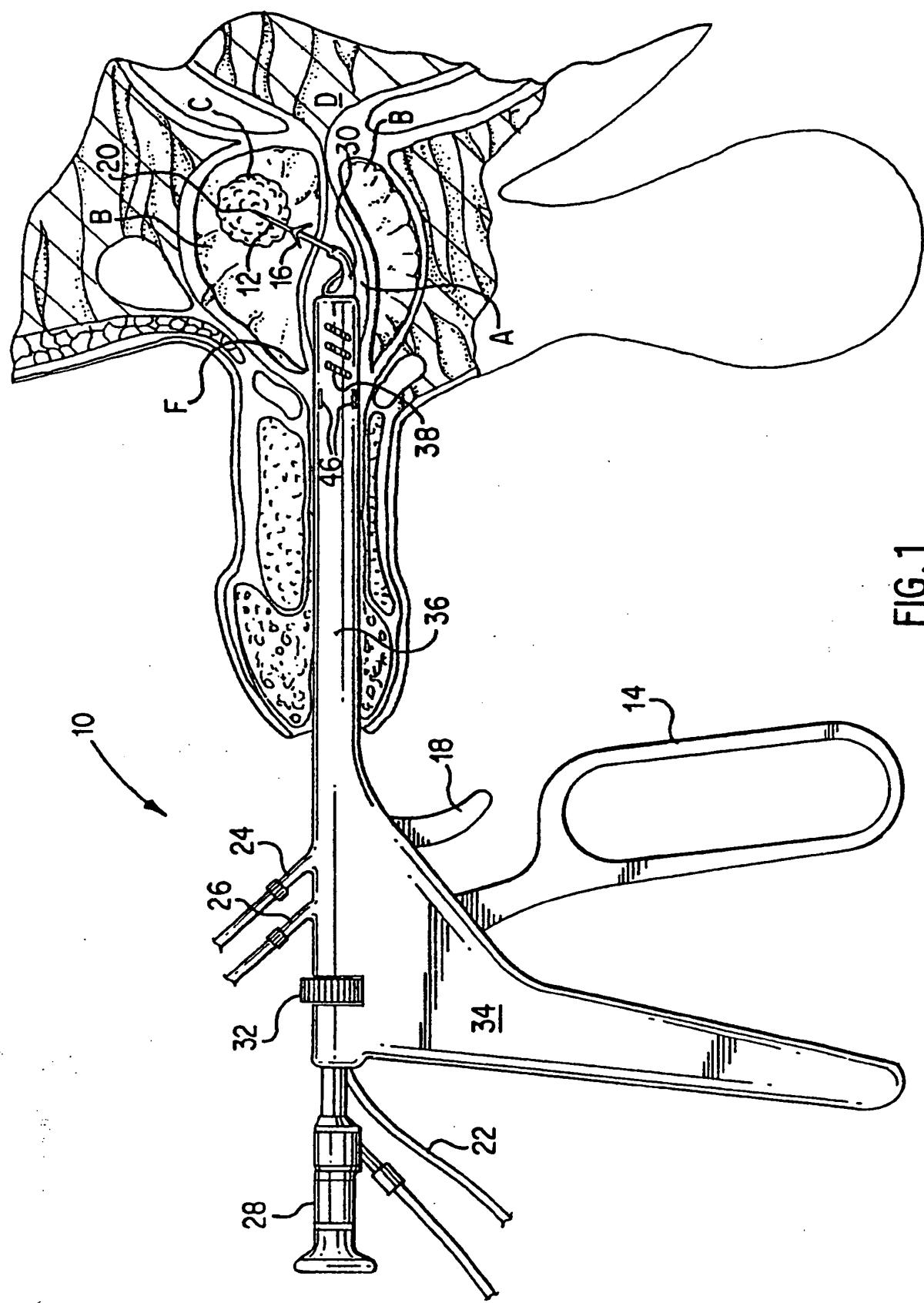
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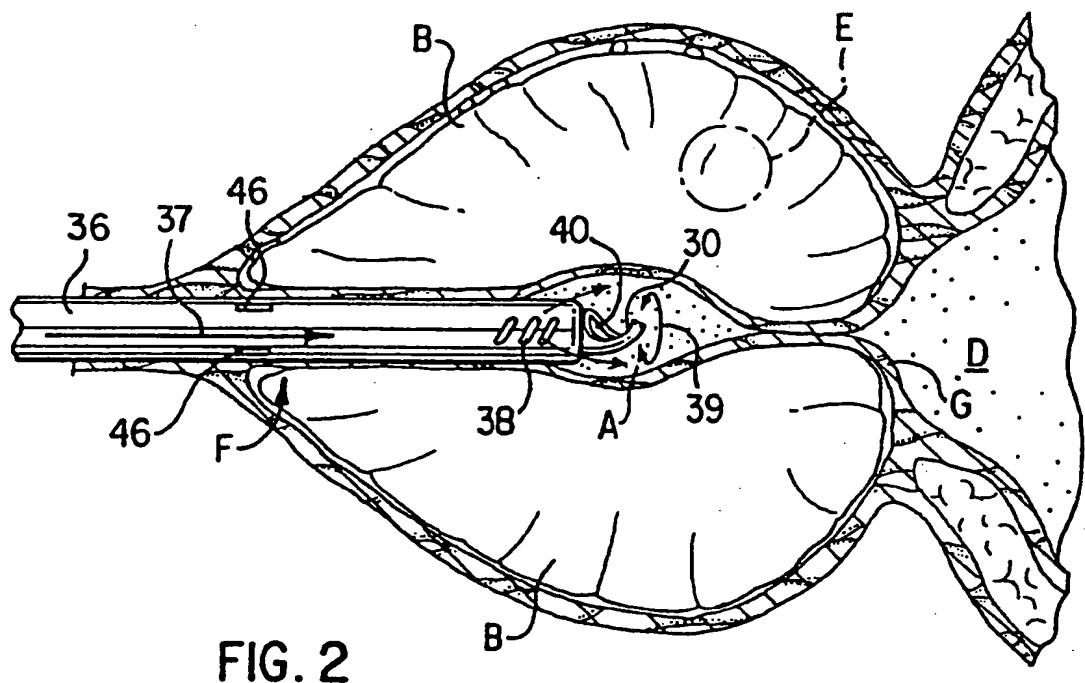


FIG. 2

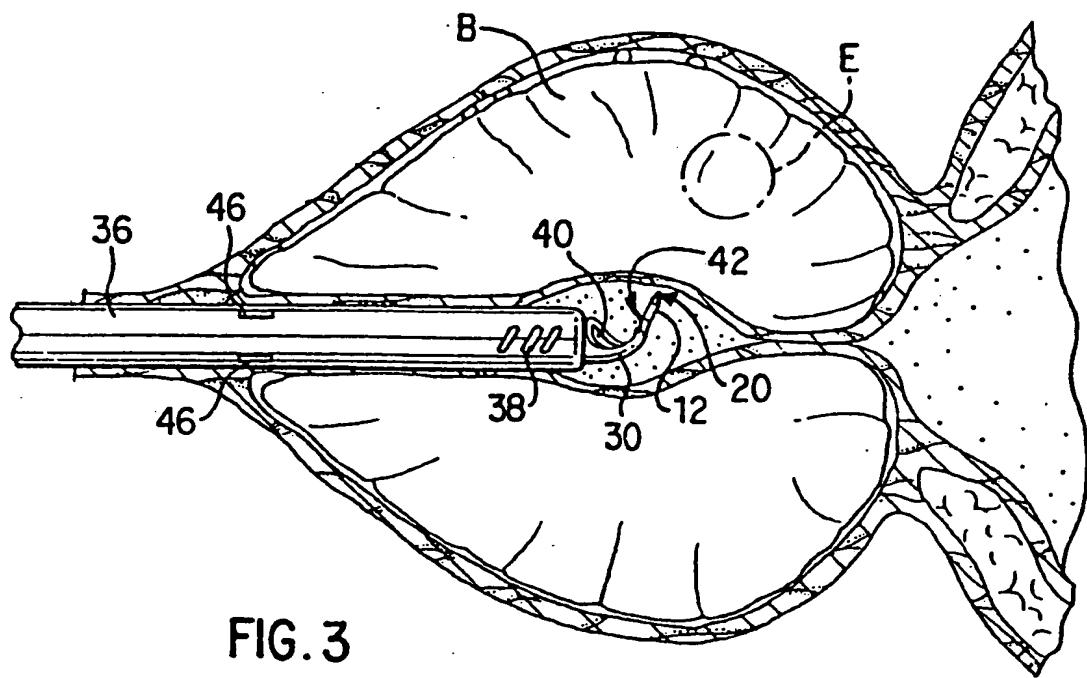


FIG. 3

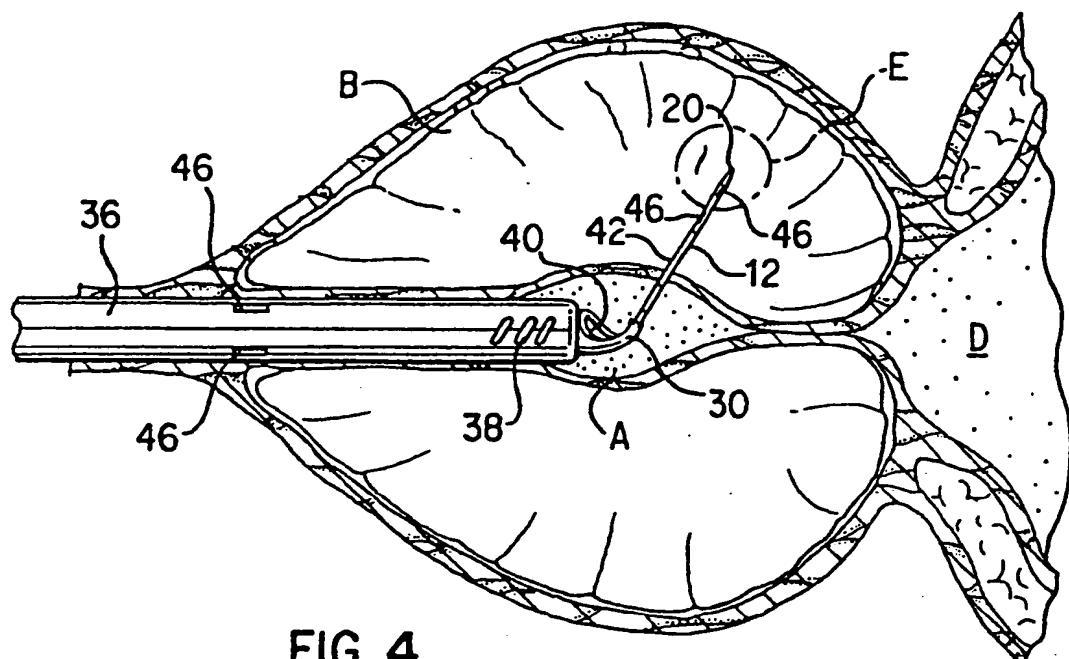


FIG. 4

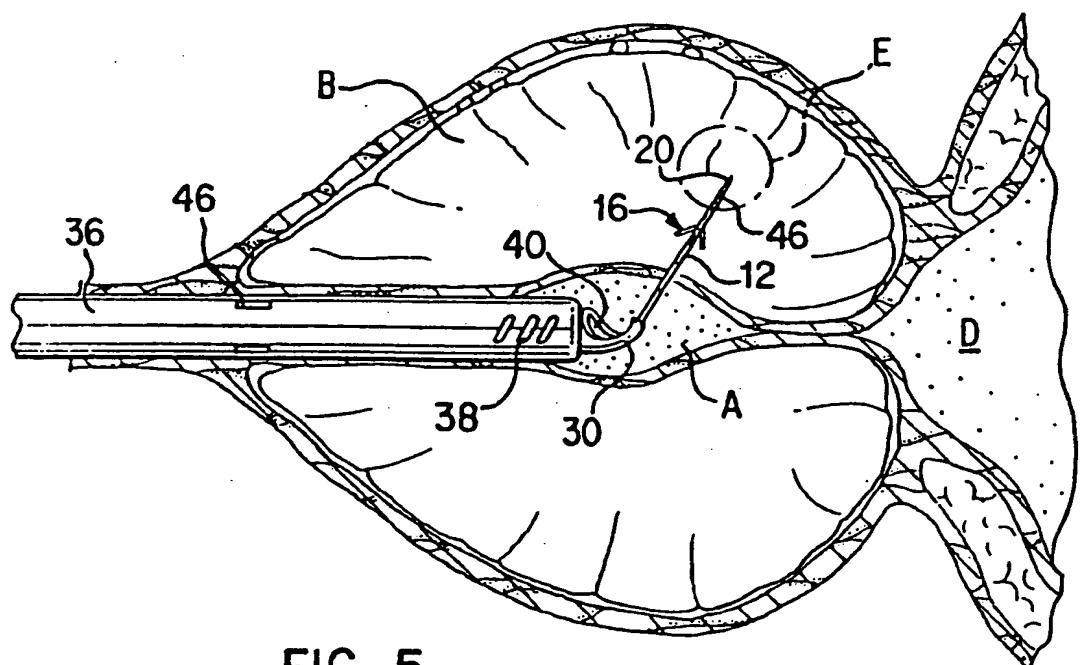


FIG. 5

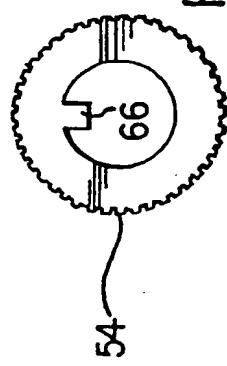


FIG. 7

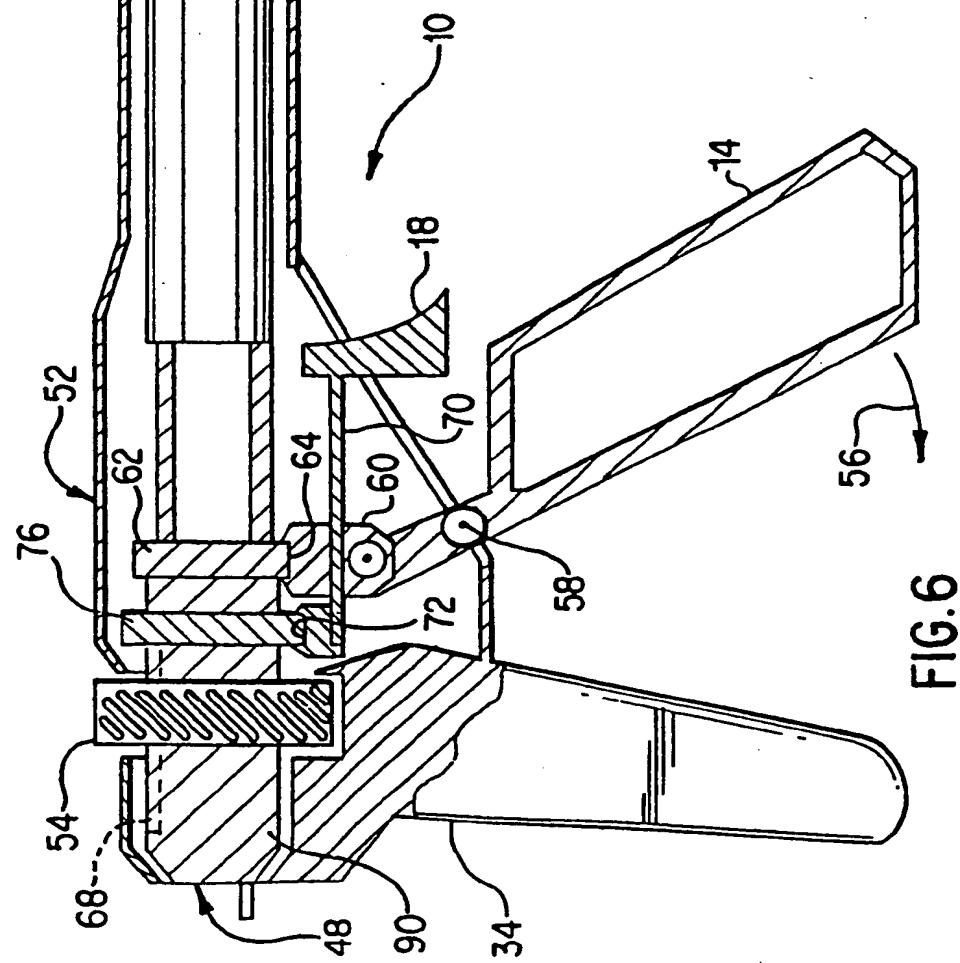


FIG. 6

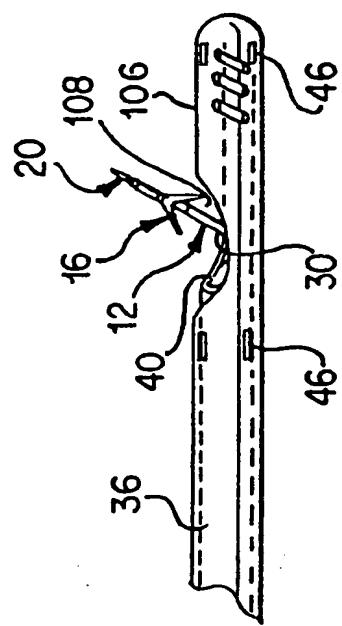


FIG. 11

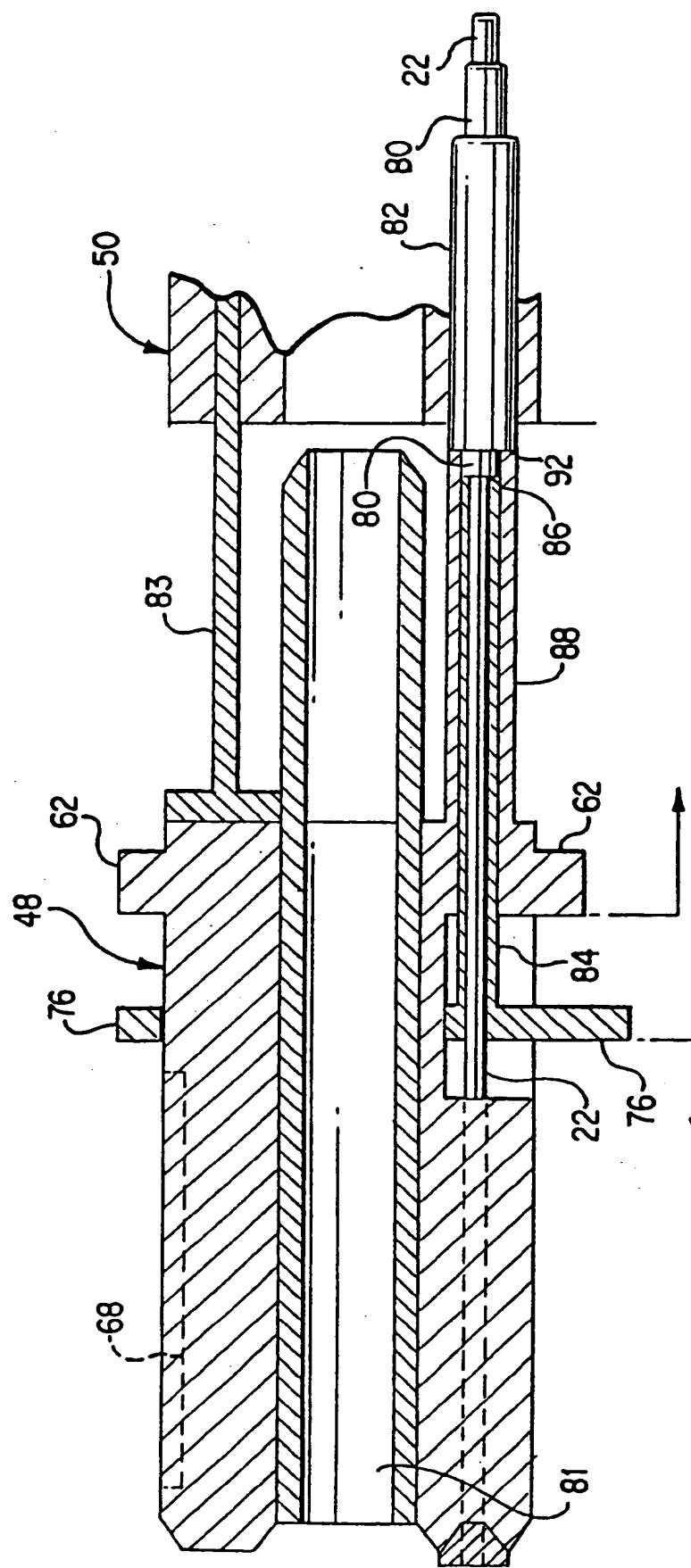
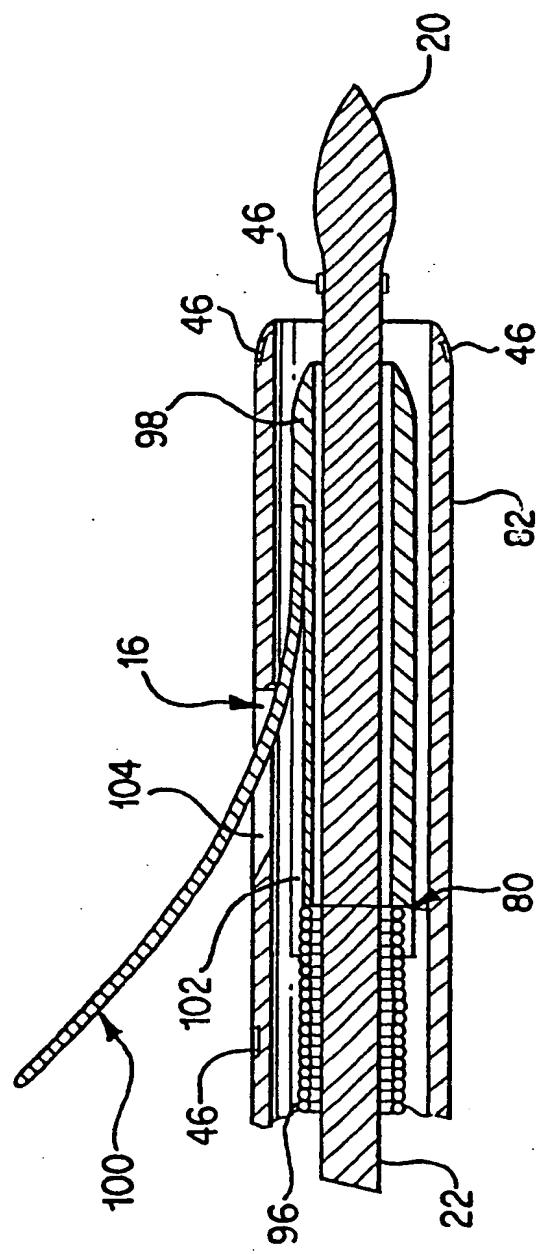
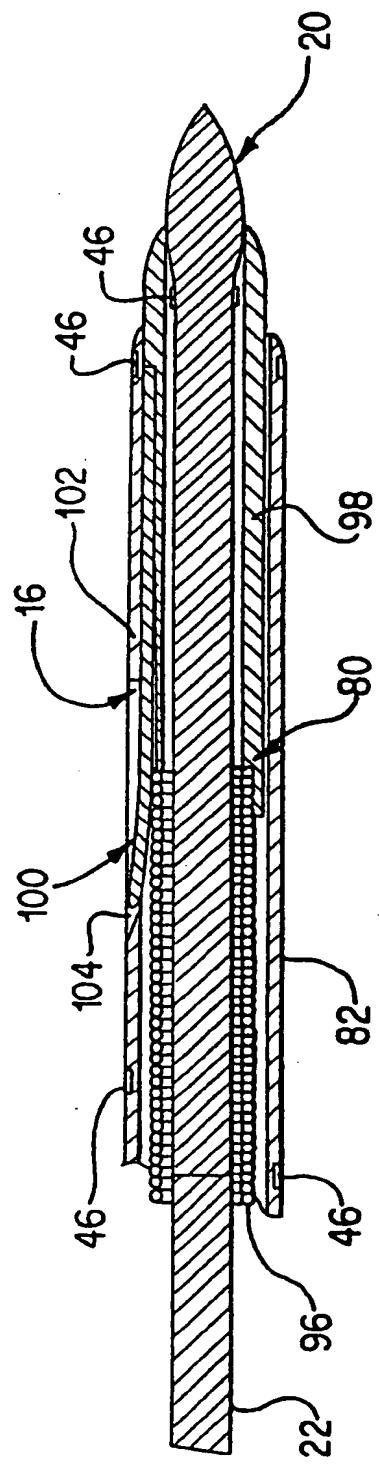


FIG. 8



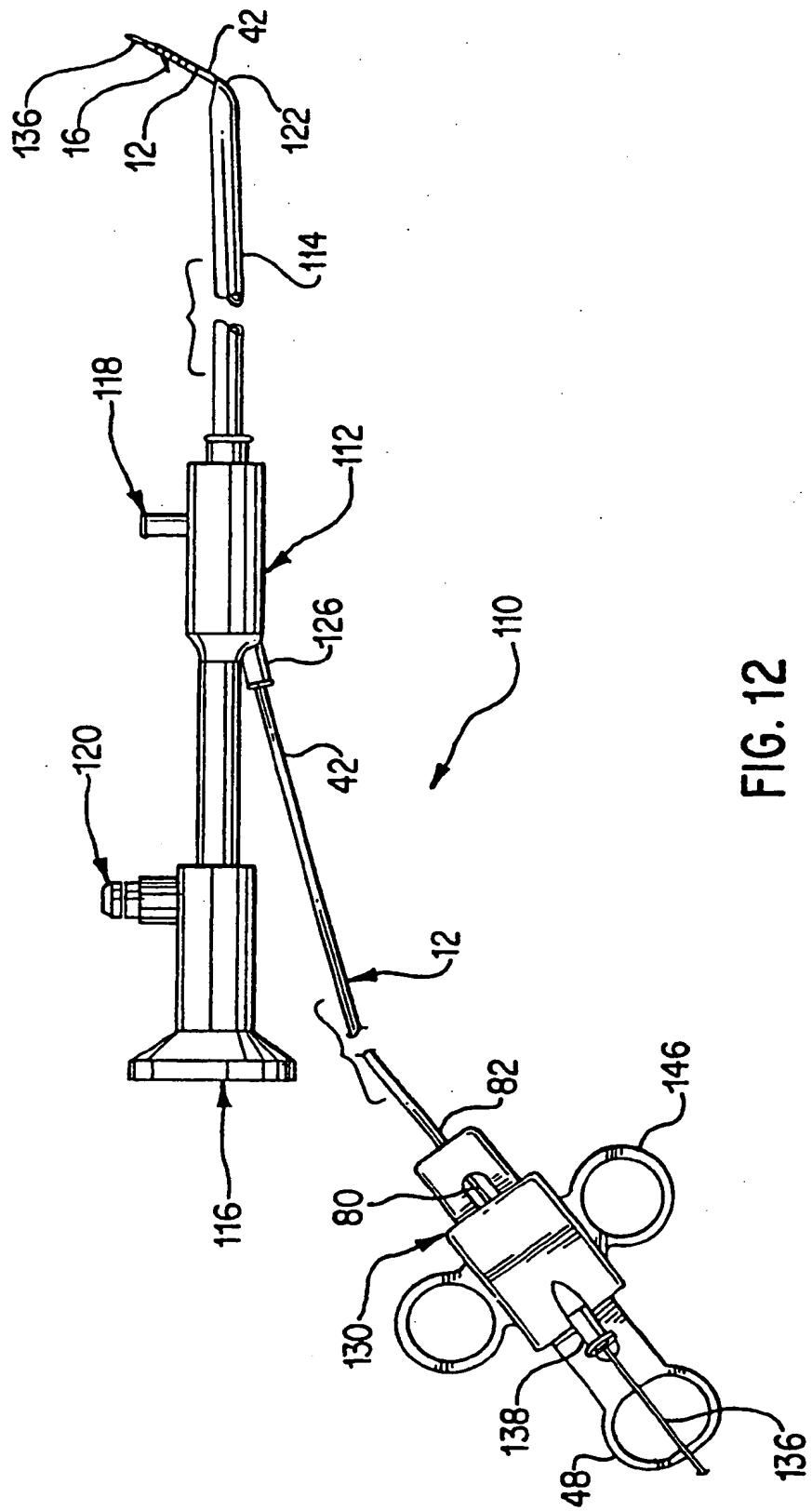
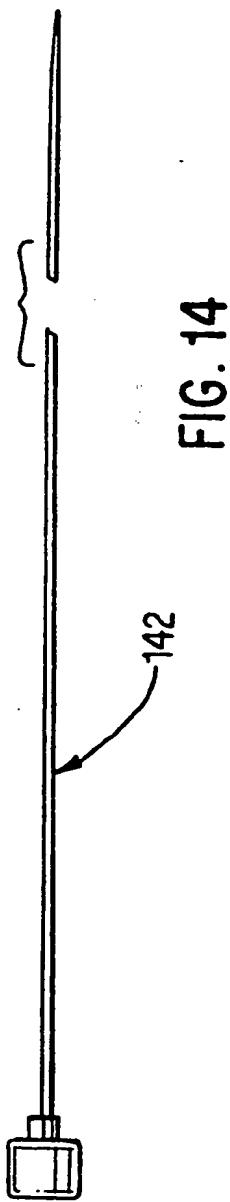
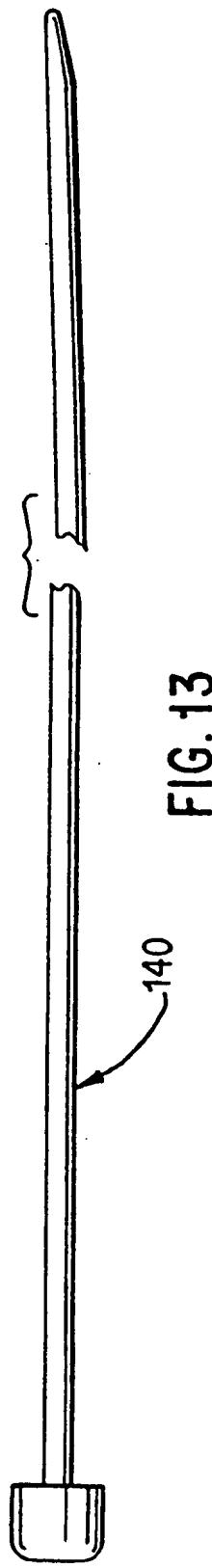
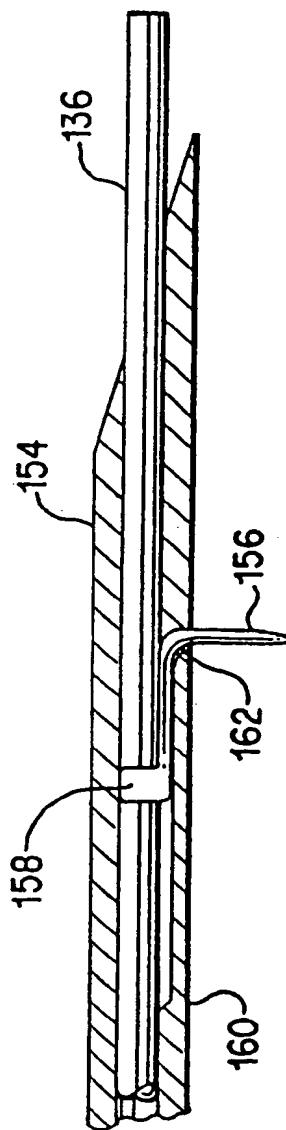
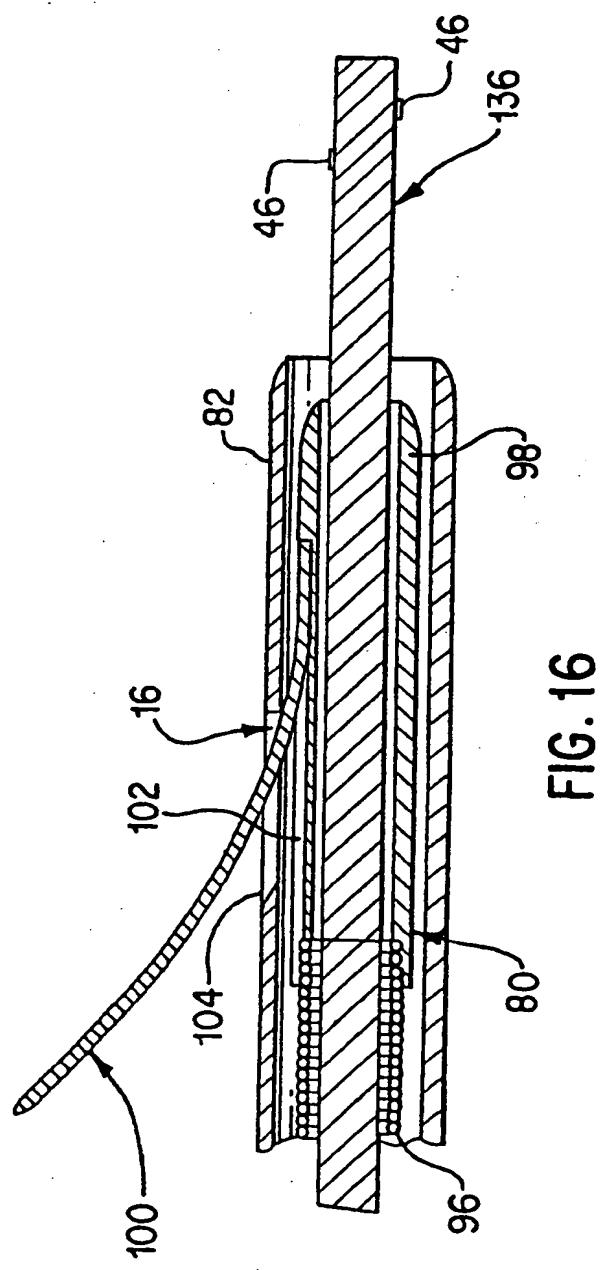
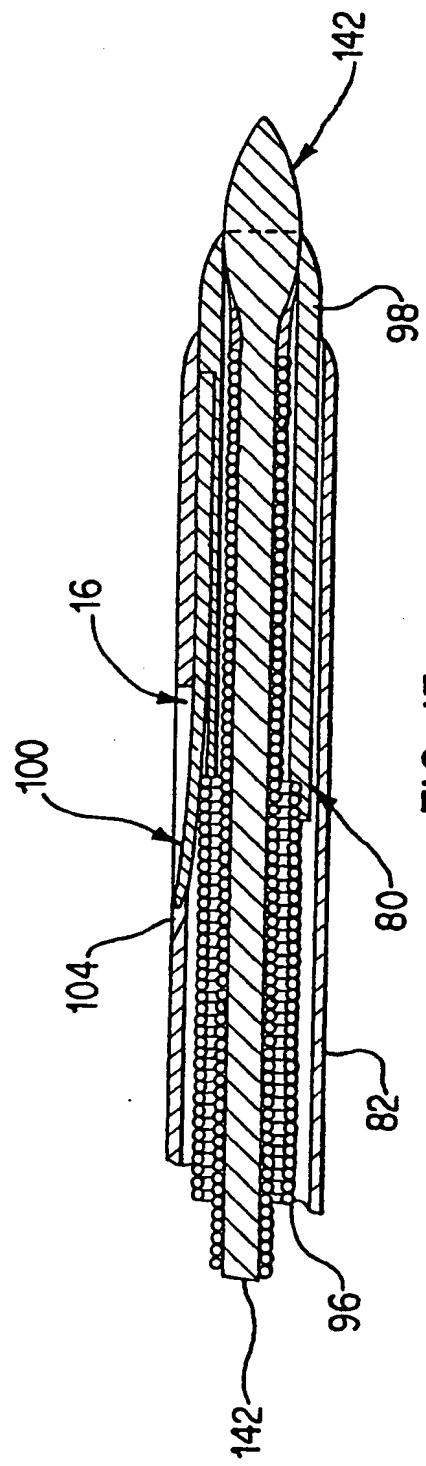
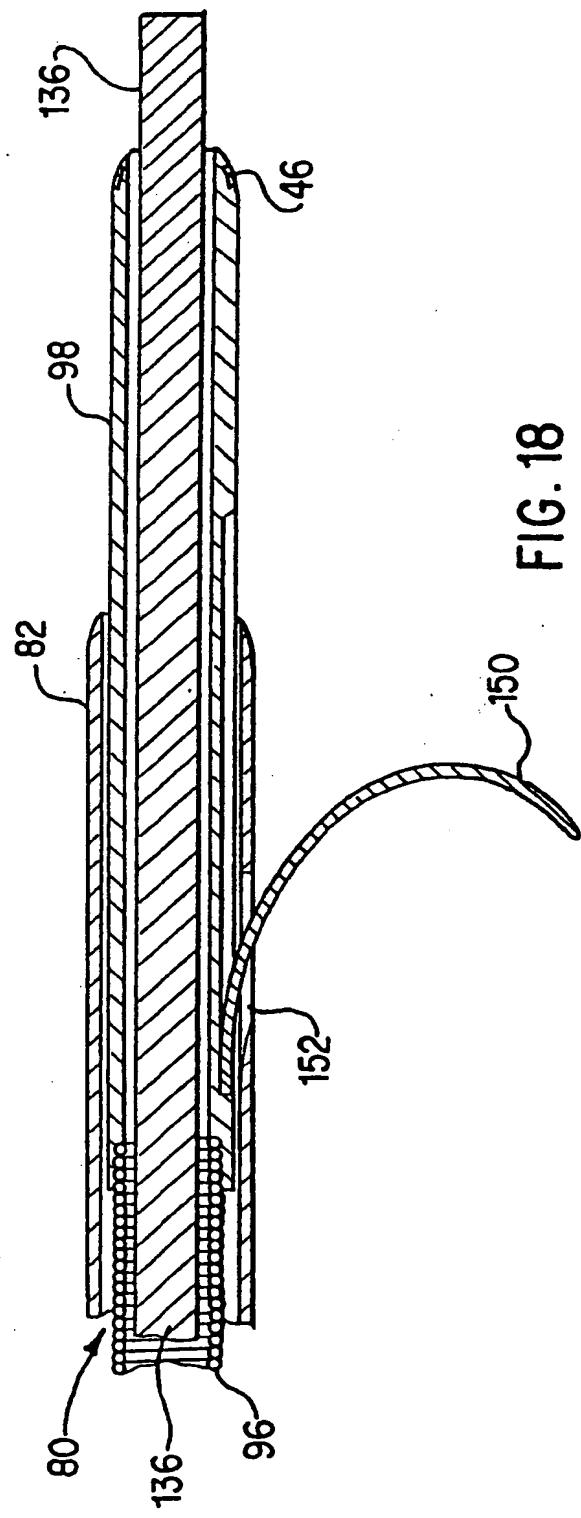
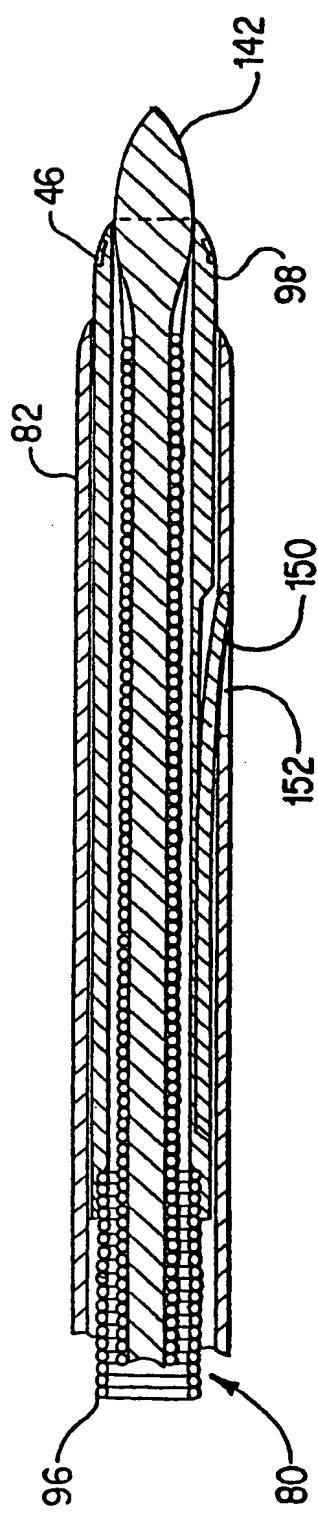


FIG. 12







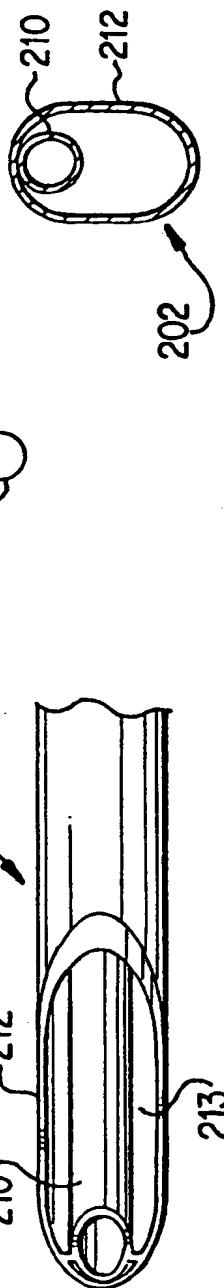
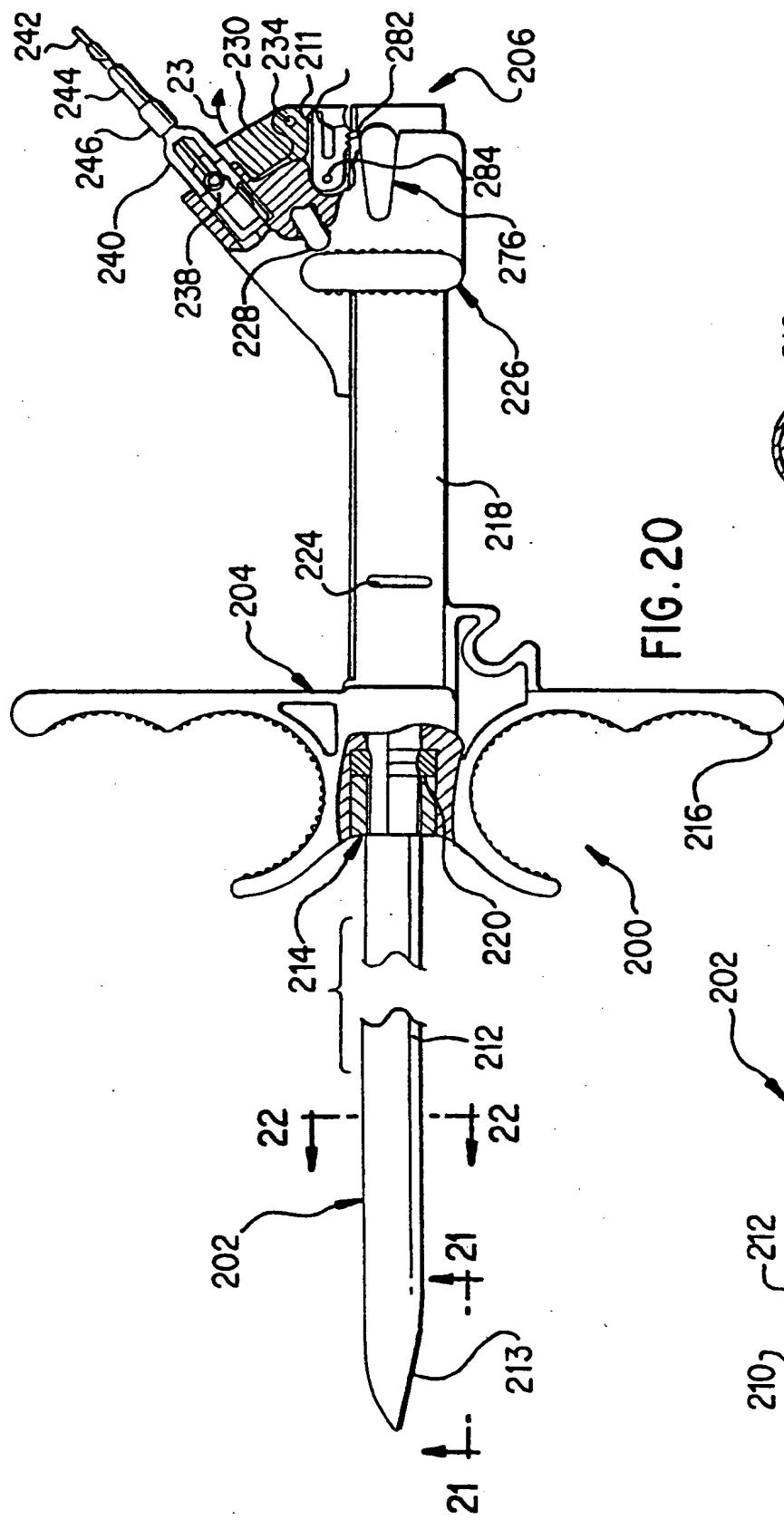


FIG. 22

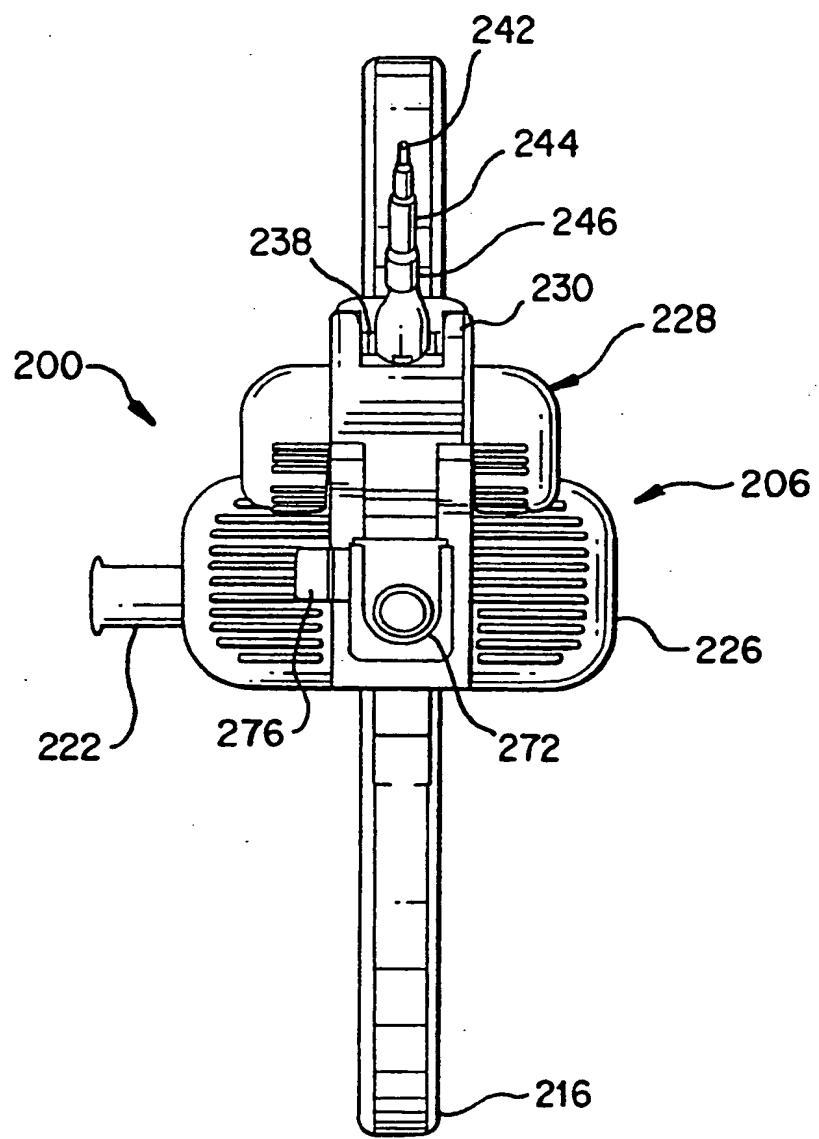


FIG. 24

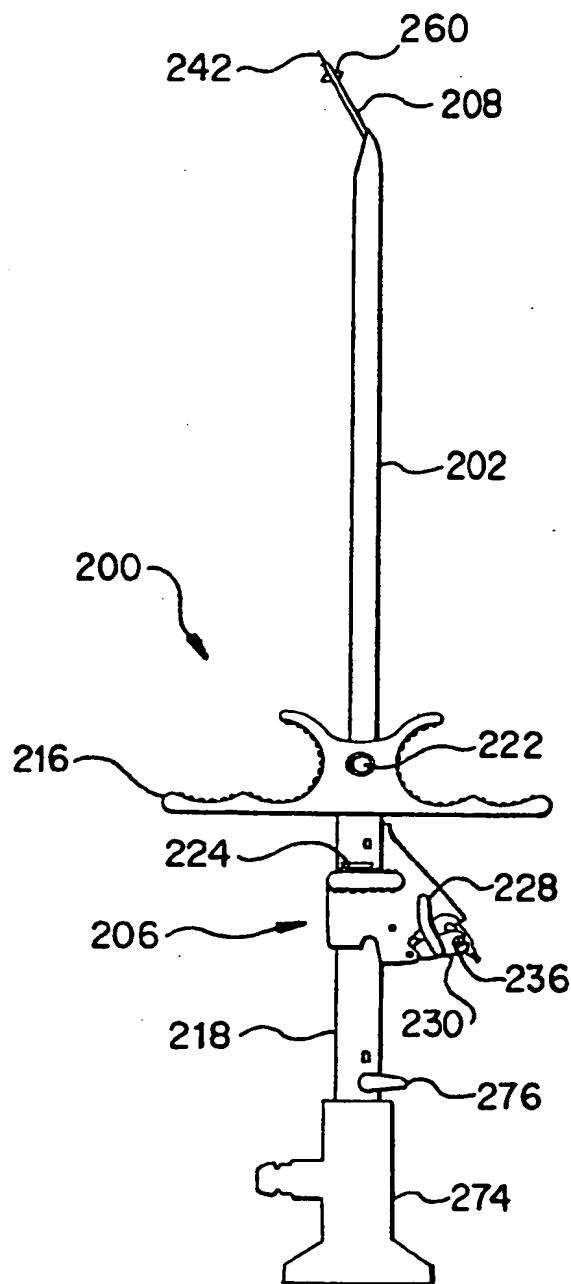


FIG. 25

**SUBSTITUTE SHEET (RULE 26)**

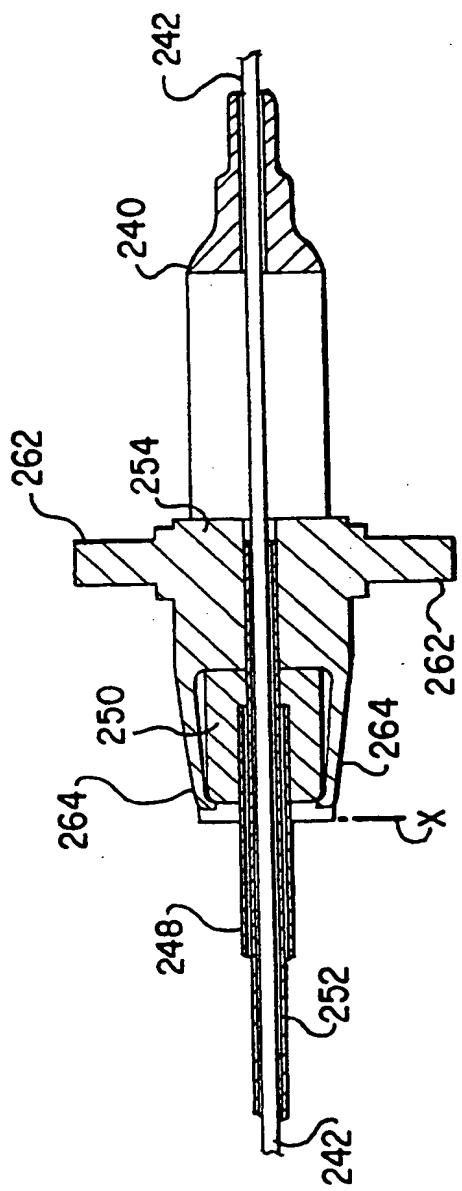


FIG. 26B

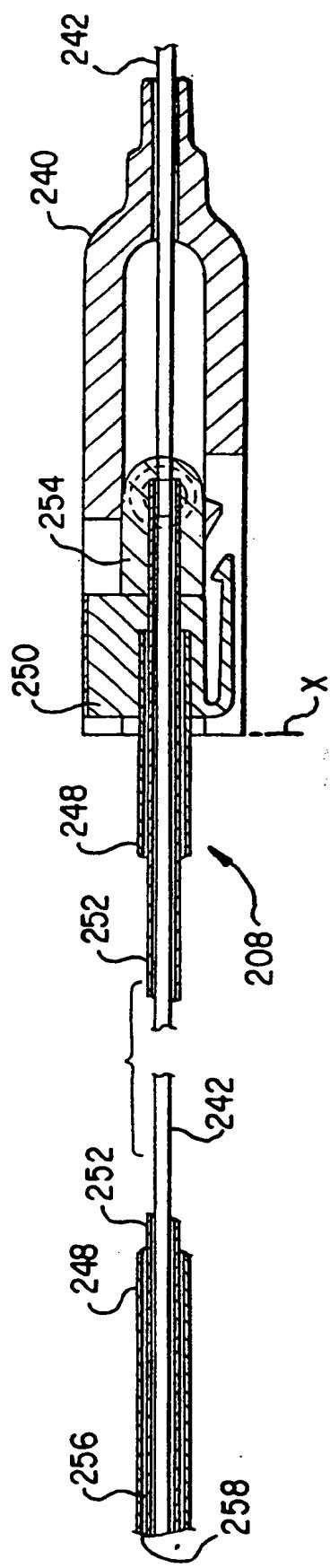


FIG. 26A

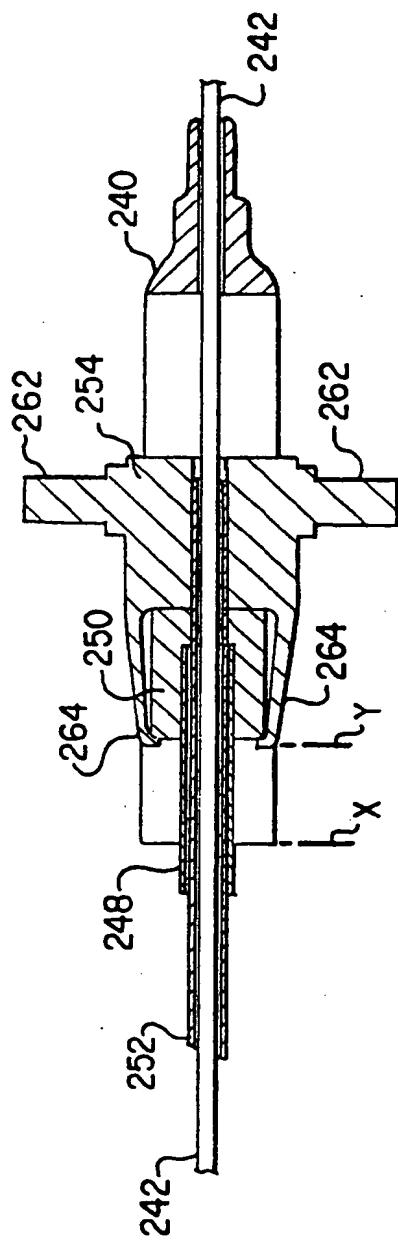


FIG. 27B

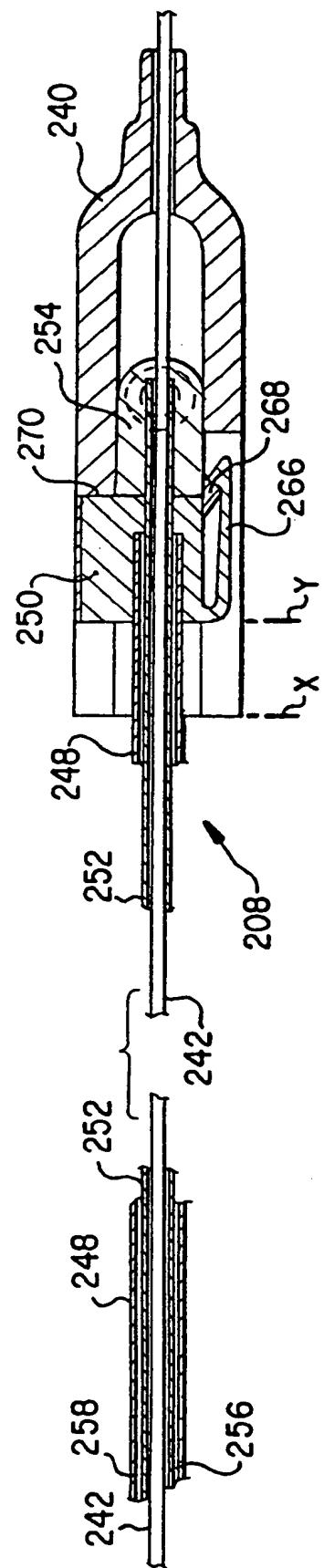


FIG. 27A

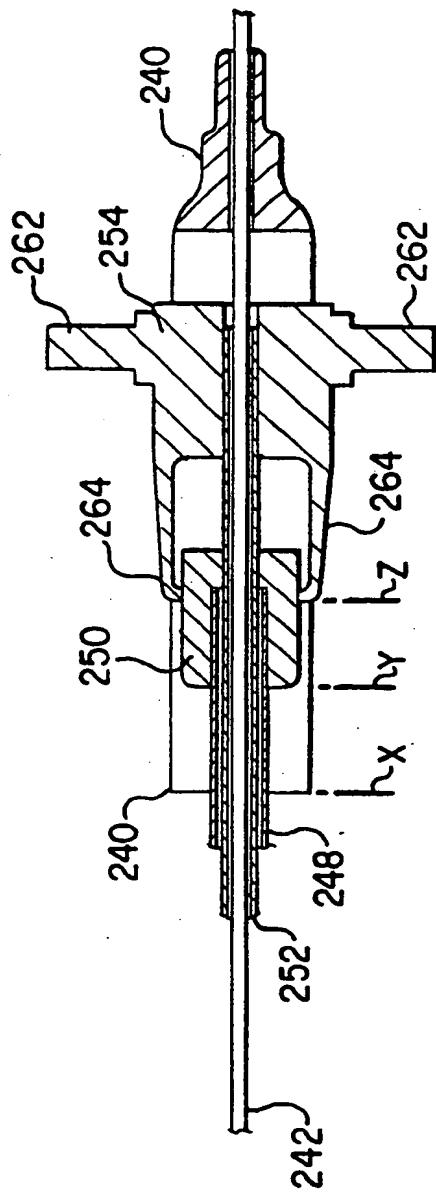


FIG. 28B

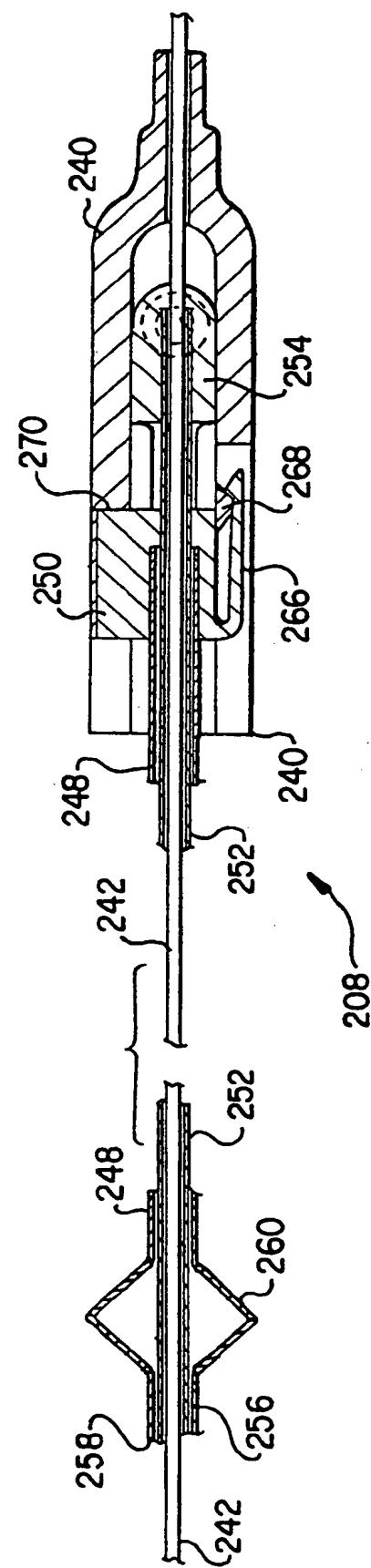


FIG. 28A

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US94/02338

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 17/36

US CL :606/15

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/104-107, 174, 175, 177, 178; 606/2-18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

None

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,862,887, (WEBER ET AL.), 05 September 1989. See the entire document.	1, 3, 5-8
Y	US, A, 4,950,267, (ISHIHARA ET AL.), 21 August 1990. See the entire document.	1-20
Y	US, A, 5,084,043, (HERTZMANN ET AL.), 28 January 1992. See the entire document.	9-14, 19
Y	EP, A, 0 189 329, (FISCHELL ET AL.), 30 July 1986. See the entire document.	2, 4, 9-20

 Further documents are listed in the continuation of Box C. See patent family annex.

• Special categories of cited documents:	
•A• document defining the general state of the art which is not considered to be part of particular relevance	•T• later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
•E• earlier document published on or after the international filing date	•X• document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
•L• document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reasons (as specified)	•Y• document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
•O• document referring to an oral disclosure, use, exhibition or other means	•&• document member of the same patent family
•P• document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

28 APRIL 1994

Date of mailing of the international search report

JUN 02 1994

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